CLINICAL TRIAL DATA TRANSPARENCY

- CURRENT PROGRESS AND MOVING TOWARDS ONE MULTI-SPONSOR ENVIRONMENT

PHUSE SDE, COPENHAGEN, 12TH JUNE 2014

Content

- All the buzz about transparency
- Timeline overview of major CTDT developments
- Key highlights and interpretations of the EMA CTDT policy
- Single-sponsor and multi-sponsor solutions – reflections and considerations
- Six Keys to success

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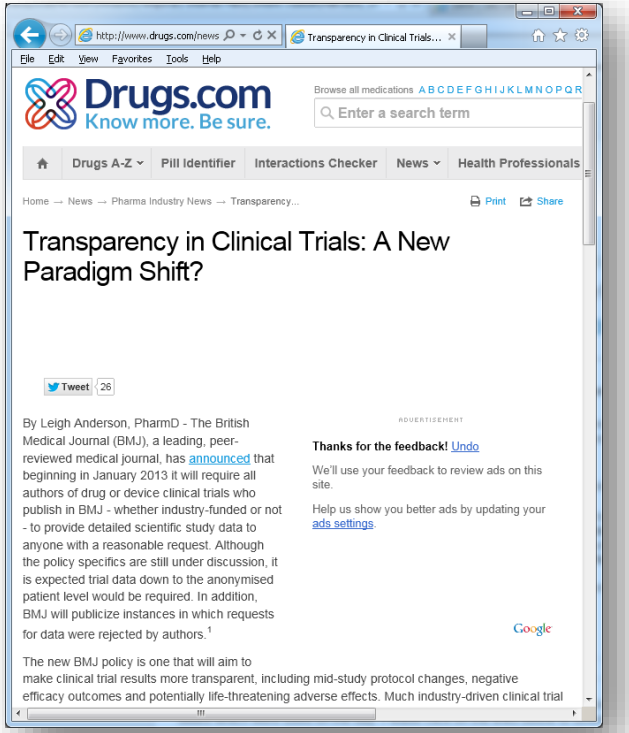
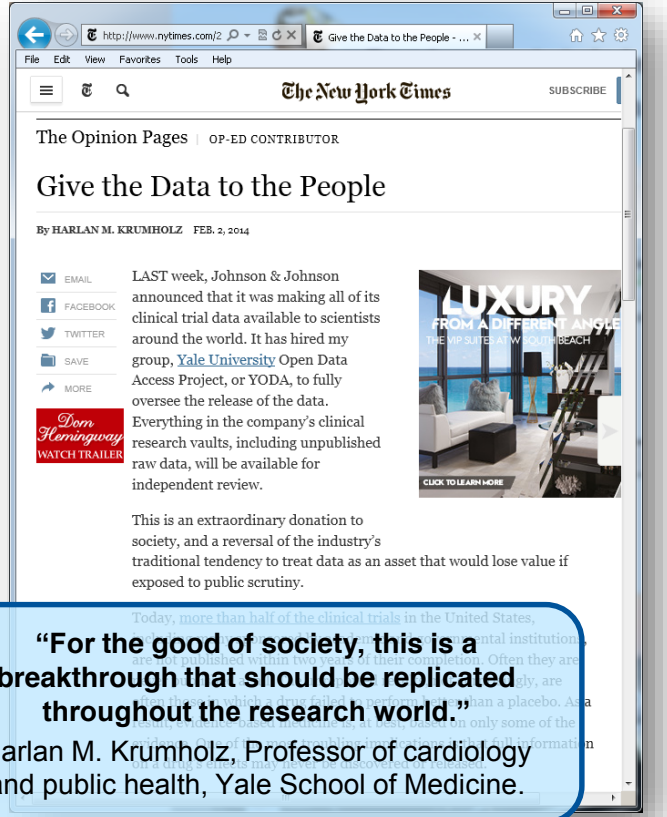
CLINICAL TRIAL DATA TRANSPARENCY

ALL THE BUZZ ABOUT TRANSPARENCY…



Source: http://www.drugs.com/news/transparency-clinical-trials-new-paradigm-shift-42128.html



"For the good of society, this is a breakthrough that should be replicated throughout the research world."

Harlan M. Krumholz, Professor of cardiology and public health, Yale School of Medicine.

Source: http://www.nytimes.com/2014/02/03/opinion/give-the-data-to-the-people.html?ribbon-ad-idx=4&rref=opinion&module=Ribbon&version=origin&region=Header&action=click&contentCollection=Opinion&pgtype=article&_r=2

CLINICAL TRIAL DATA TRANSPARENCY

WHAT'S DRIVING THE CONVERSATION

- When manufacturers seek approval for new medications and therapies, they deliver data and associated evidence to country regulatory authorities (FDA, EMA, etc.)

- That (patient-level) data is typically unavailable to anyone besides the company that submitted it, and the regulators.

- Draft guidance from the EMA created urgency within the industry to address transparency.
  - "*The policy was discussed at the March 2014 Management Board meeting. The final policy and an implementation plan will be presented to the Management Board for endorsement at its June 2014 meeting.*"*

- The biopharmaceutical industry is changing their expectations about managing this historically proprietary data.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency, London

*Source:http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp&mid=WC0b01ac0580614159

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CLINICAL TRIAL DATA TRANSPARENCY

Q4 2012

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2012/07/event_detail_000656.jsp&mid=WC0b01ac058004d5c3

Advisory groups

The five **advisory groups** addressed the following topics:

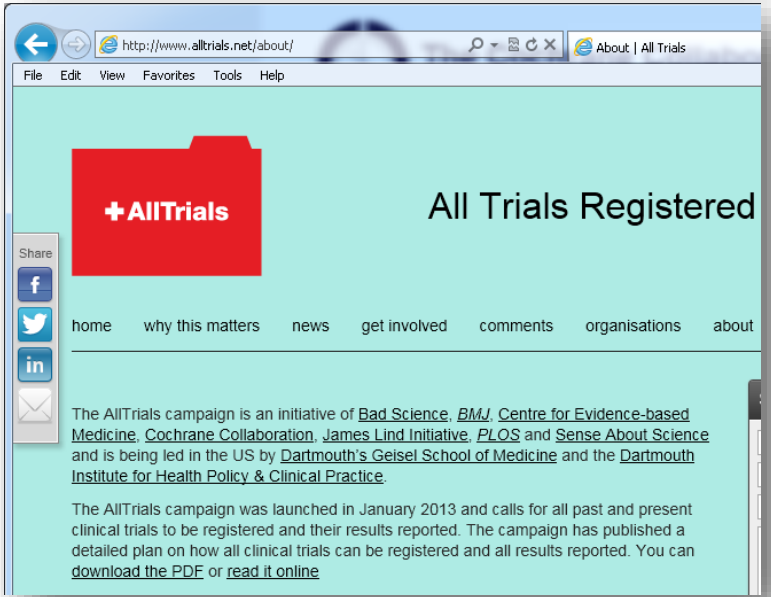
Advisory group	Topics
Protecting patient confidentiality	How can the Agency ensure through its policy that patient and other personal information will be adequately protected, i.e. that patients cannot be retroactively identified when clinical-trial data are released, and that applicable legislation, standards, and rules regarding personal data protection will be respected?
Clinical-trial-data formats	How can the Agency ensure through its policy that clinical-trial data can be shared, in the interests of public health, in a clear and understandable format that enables appropriate analyses and a swift implementation without undue burden to stakeholders?
Rules of engagement	Are there rules or conditions that should be in place before an external stakeholder can download clinical-trial data (e.g. formal acceptance of the need to respect personal data rules, uploading of analysis plans etc.)?
Good analysis practice	Are there good-analysis-practice guidelines that the Agency could ask external requestors of data to consider or be aware of, and that the Agency can apply when confronted with additional analyses from external parties?
Legal aspects	Are there any legal aspects other than personal data protection that need to be addressed when drafting the Agency's policy? Are there exceptional circumstances under which data can be claimed to be commercially confidential?

http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000556.jsp&mid=WC0b01ac0580614159

CLINICAL TRIAL DATA TRANSPARENCY

Q4 2012 - Q1-2013

http://www.forbes.com/sites/matthewherper/2012/10/11/with-transparency-pledge-glaxo-makes-promises-no-other-drug-company-has/



http://www.alltrials.net/about/

CLINICAL TRIAL DATA TRANSPARENCY

SUMMER 2013

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2013
EMA/240810/2013
Executive Director

Publication and access to clinical-trial data

POLICY/0070
Status: Draft for public consultation
Effective date:
Review date:
Supersedes: N.A.

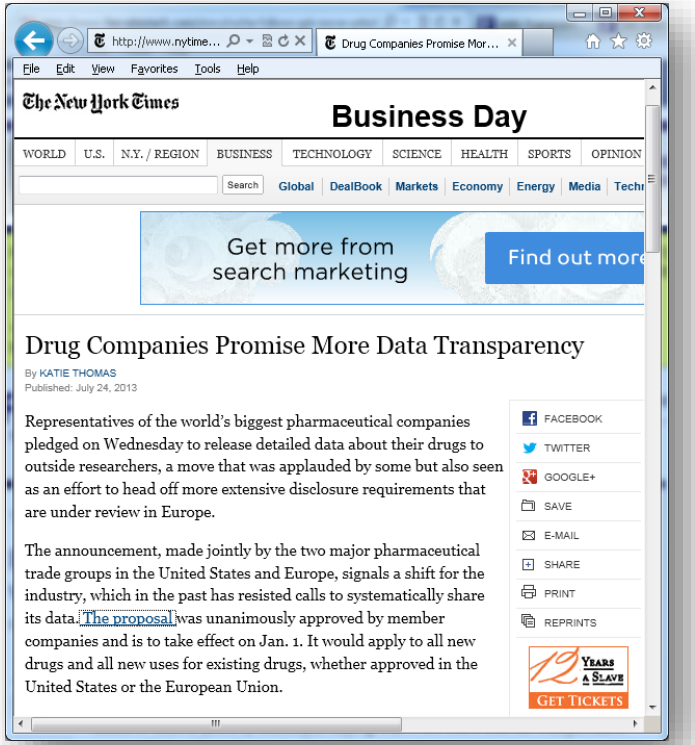
1. Introduction and purpose

The aim of the European Medicines Agency ('the Agency') is to protect and foster public health. Transparency is a key consideration for the Agency in delivering its service to patients and society.

There is growing demand from external stakeholders for full transparency, not only about the Agency's deliberations and actions, but also about the data and results from clinical trials (CTs) on which regulatory decisions are based. Following consultations with a broad range of external stakeholders and European bodies, including the European Ombudsman and the European Data Protection Supervisor, the Agency has drafted this policy, which complements the existing 'Policy on access to documents (related to medicinal products for human and veterinary use)' (POLICY/0043) (EMA/110196/2006), which came into effect in December 2010. To ensure consistency, the existing policy on access to documents and this policy on publication and access to clinical-trial data, once finalised, will be aligned.

DRAFT

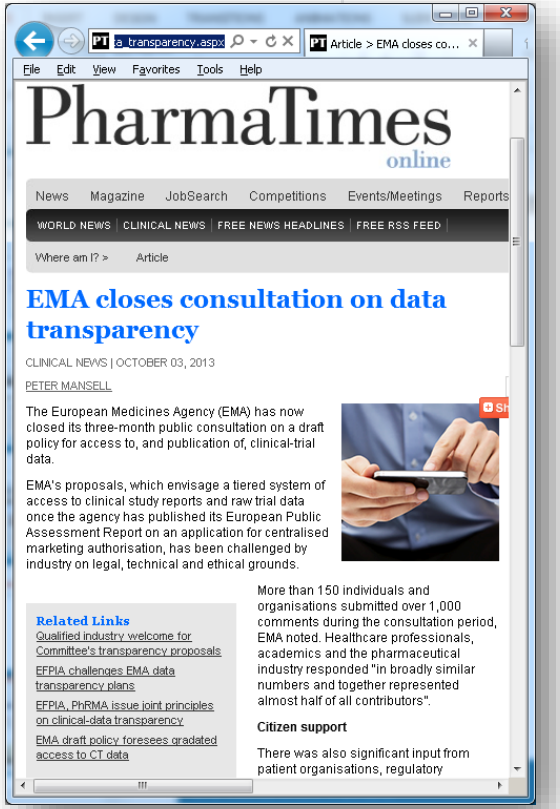
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/06/WC500144730.pdf



http://www.nytimes.com/2013/07/25/business/drug-companies-promise-more-data-transparency.html?_r=0

CLINICAL TRIAL DATA TRANSPARENCY

Q3/Q4-2013



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Where am I? » Article

EMA closes consultation on data transparency

CLINICAL NEWS | OCTOBER 03, 2013

PETER MANSELL

The European Medicines Agency (EMA) has now closed its three-month public consultation on a draft policy for access to, and publication of, clinical-trial data.

EMA's proposals, which envisage a tiered system of access to clinical study reports and raw trial data once the agency has published its European Public Assessment Report on an application for centralised marketing authorisation, has been challenged by industry on legal, technical and ethical grounds.

More than 150 individuals and organisations submitted over 1,000 comments during the consultation period, EMA noted. Healthcare professionals, academics and the pharmaceutical industry responded "in broadly similar numbers and together represented almost half of all contributors".

Citizen support

There was also significant input from patient organisations, regulatory

Related Links

Qualified industry welcome for Committee's transparency proposals

EFPIA challenges EMA data transparency plans

EFPIA, PhRMA issue joint principles on clinical-data transparency

EMA draft policy foresees gradated access to CT data

http://www.pharmatimes.com/article/13-10-03/EMA_closes_consultation_on_data_transparency.aspx

BERLINGSKE BUSINESS

INVESTOR ØKONOMI GLOBAL BRANCHER VÆKST KARRIERE PRIVATØ

MEDICO

Novo og Leo giver adgang til forsøgsdata

Af Vibeke L. Svansø
4. november 2013, 22:30

Novo Nordisk og Leo Pharma giver efter for internationalt pres og øger frivilligt adgangen til resultaterne af selskabets medicinforsøg.

DEL ARTIKLEN

Print Mail

Anbefal 1

SE OGSÅ

Øv-sager presser Novo Nordisk til mere åbenhed

Europæisk agentur vil gå længere endnu

Analyse: Novo skuffer men har langsigtet

Novo Nordisk og Leo Pharma følger nu trop med de to europæiske medicinal-giganter GlaxoSmithKline og Roche og vil fremover frivilligt dele resultater af medicinforsøg med patienter og forskere.

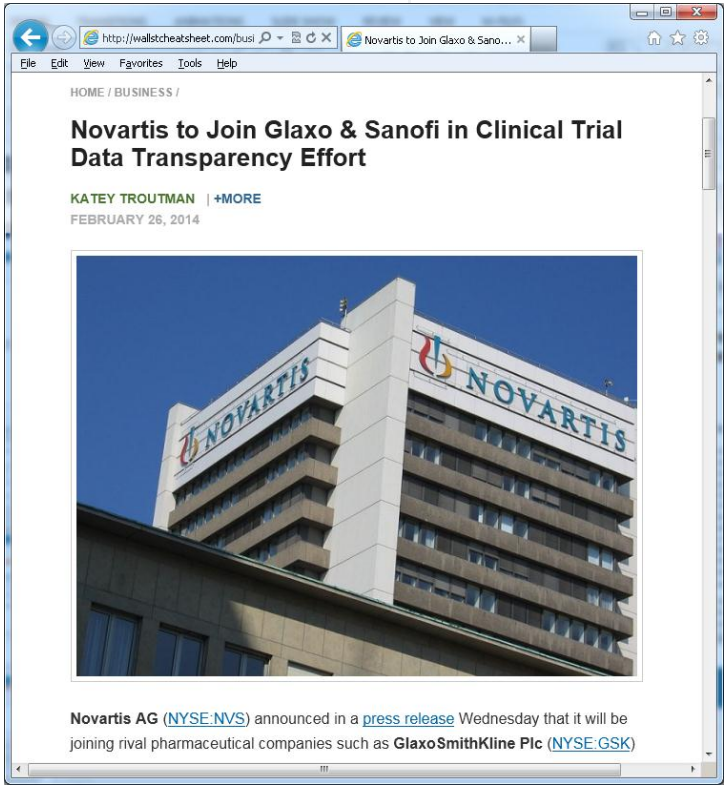
Det sker ved at offentliggøre kliniske studierapporter på nettet og ved at give forskere mulighed for at søge et uafhængigt videnskabeligt panel om adgang til rådata. Den nye åbenhed om medicinforsøg hos Danmarks største og tredjestørste medicinalselskab kommer efter flere års stigende pres mod medicinalindustrien om øget offentlighed.

Netop nu er emnet genstand for en ophedet debat i EU-regi, efter at det europæiske lægemiddelagentur, EMA, tidligere på året fremlagde et forslag til en ny offentlighedspolitik, som vil give udstrakt adgang til forsøgsrapporter og rådata. Forslaget skal efter planen vedtages i december med virkning fra 1. januar 2014.

http://www.business.dk/medico/novo-og-leo-giver-adgang-til-forsoegsdata

CLINICAL TRIAL DATA TRANSPARENCY

Q1-2014



HOME / BUSINESS /

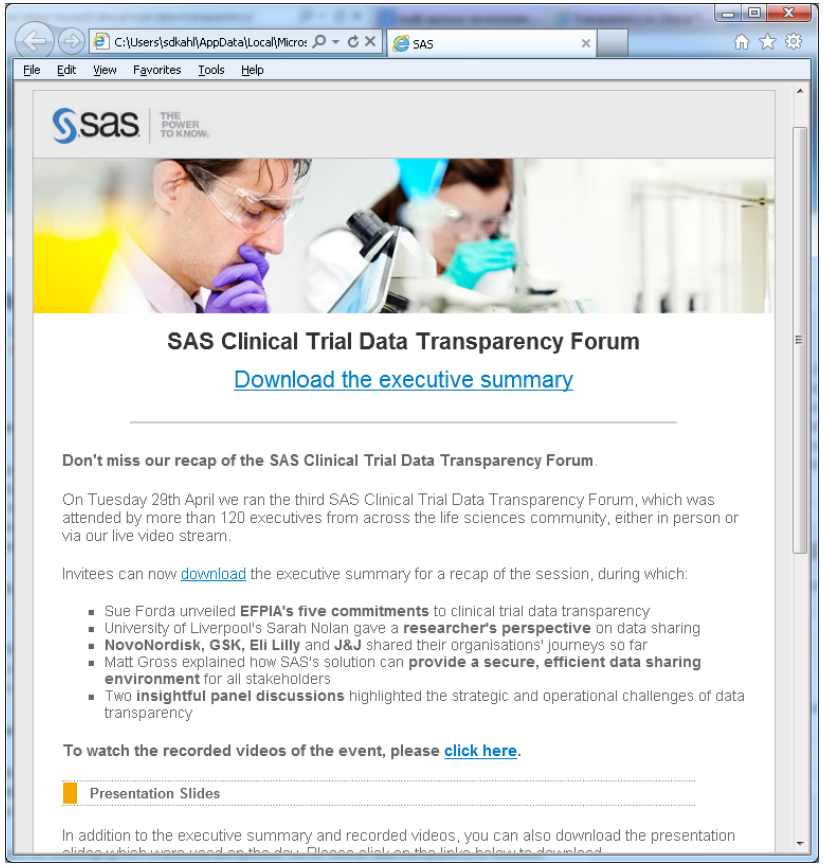
Novartis to Join Glaxo & Sanofi in Clinical Trial Data Transparency Effort

KATEY TROUTMAN | +MORE

FEBRUARY 26, 2014

Novartis AG (NYSE:NVS) announced in a press release Wednesday that it will be joining rival pharmaceutical companies such as **GlaxoSmithKline Plc** (NYSE:GSK)

Source: http://wallstcheatsheet.com/business/novartis-to-join-glaxo-sanofi-in-clinical-trial-data-transparency-effort.html/?a=viewall



SAS Clinical Trial Data Transparency Forum

Download the executive summary

Don't miss our recap of the SAS Clinical Trial Data Transparency Forum.

On Tuesday 29th April we ran the third SAS Clinical Trial Data Transparency Forum, which was attended by more than 120 executives from across the life sciences community, either in person or via our live video stream.

Invitees can now download the executive summary for a recap of the session, during which:

- Sue Forda unveiled **EFPIA's five commitments** to clinical trial data transparency
- University of Liverpool's Sarah Nolan gave a **researcher's perspective** on data sharing
- **NovoNordisk, GSK, Eli Lilly** and **J&J** shared their organisations' journeys so far
- Matt Gross explained how SAS's solution can **provide a secure, efficient data sharing environment** for all stakeholders
- Two **insightful panel discussions** highlighted the strategic and operational challenges of data transparency

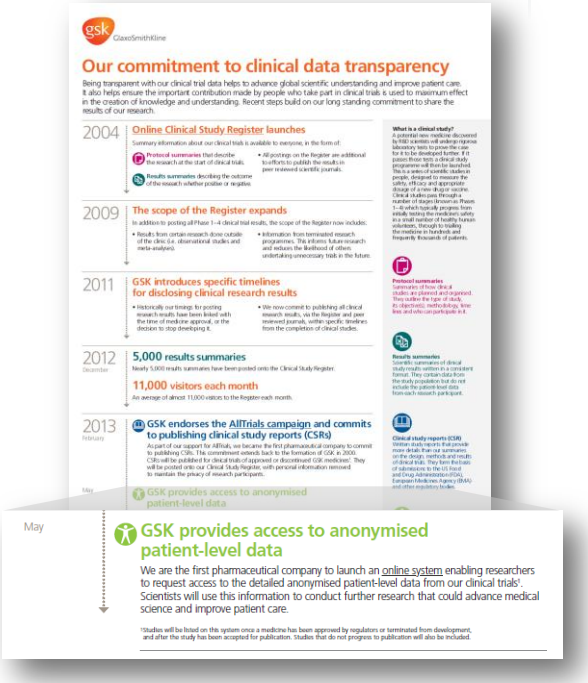
To watch the recorded videos of the event, please click here.

Presentation Slides

In addition to the executive summary and recorded videos, you can also download the presentation

CLINICAL TRIAL DATA TRANSPARENCY

THE JOURNEY UNTIL NOW


GlaxoSmithKline

Our commitment to clinical data transparency

Being transparent with our clinical trial data helps to advance global scientific understanding and improve patient care. It also helps ensure the important contribution made by people who take part in clinical trials is used to maximum effect in the creation of knowledge and understanding. Recent steps build on our long standing commitment to share the results of our research.

2004 Online Clinical Study Register launches

Summary information about our clinical trials is available to everyone, in the form of:

- Protocol summaries that describe the research at the start of clinical trials
- Results summaries describing the outcome of the research whether positive or negative
- All postings on the Register are additional to efforts to publish the results in peer reviewed scientific journals.

2009 The scope of the Register expands

In addition to posting all Phase 1–4 clinical trial results, the scope of the Register now includes:

- Results from certain research done outside of the clinic (i.e., observational studies and meta-analyses).
- Information from terminated research programmes. This informs future research and reduces the likelihood of others undertaking unnecessary trials in the future.

2011 GSK introduces specific timelines for disclosing clinical research results

- Historically our timings for posting research results have been linked with the time of medicine approval, or the decision to stop developing it.
- We now commit to publishing all clinical research results, via the Register and peer reviewed journals, within specific timelines from the completion of clinical studies.

2012 December

5,000 results summaries

Nearly 5,000 results summaries have been posted onto the Clinical Study Register.

11,000 visitors each month

An average of almost 11,000 visitors to the Register each month.

2013 February

GSK endorses the AllTrials campaign and commits to publishing clinical study reports (CSRs)

As part of our support for AllTrials, we became the first pharmaceutical company to commit to publishing CSRs. This commitment extends back to the formation of GSK in 2000. CSRs will be published for clinical trials of approved or discontinued GSK medicines[1]. They will be posted onto our Clinical Study Register, with personal information removed to maintain the privacy of research participants.

May

GSK provides access to anonymised patient-level data

We are the first pharmaceutical company to launch an online system enabling researchers to request access to the detailed anonymised patient-level data from our clinical trials[1]. Scientists will use this information to conduct further research that could advance medical science and improve patient care.

[1]Studies will be listed on this system once a medicine has been approved by regulators or terminated from development, and after the study has been accepted for publication. Studies that do not progress to publication will also be included.

What is a clinical study?

A potential new medicine discovered in the laboratory undergoes rigorous laboratory tests to prove the case for it to be developed further. If it passes those tests a clinical study programme will then be launched. This is a series of scientific studies in people, designed to measure the safety, efficacy, pharmacology and dosage of a new drug or vaccine. Clinical studies pass through a number of stages (known as Phases 1–4) which typically progress from initially testing the medicine's safety in a small number of healthy human volunteers, to finally testing the medicine in hundreds and frequently thousands of patients.

Protocol summaries

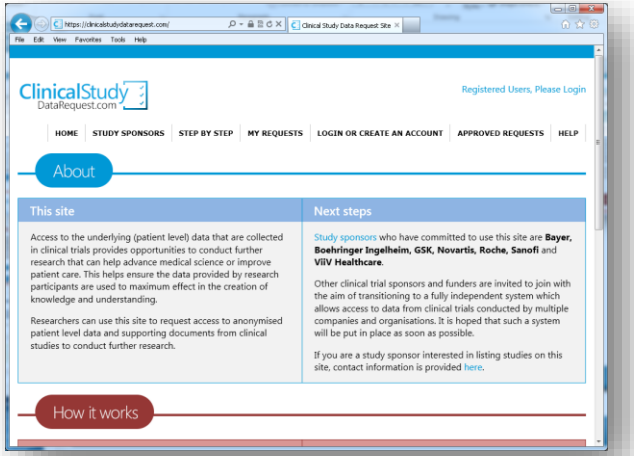
Summaries of how clinical studies are planned and organised. They outline the type of study, its objective(s), methodology, time lines and who can participate in it.

Results summaries

Scientific summaries of clinical study results written in a consistent format. They contain data from the study population but do not include the patient-level data from each research participant.

Clinical study reports (CSR)

Written study reports that provide detailed, full, scientific information on the design, methods and results of clinical trials. They form the basis of submissions to the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory bodies.



- SAS facilitating dialog in industry (multiple webinars and forums)
- Meetings with data transparency owners at many major pharmas
- Ongoing roundtable discussions (LinkedIn)

- 8 out of global top 20 pharmas have chosen SAS solution

- Industry is moving towards a multi-company initiative on a shared, clinical trial data transparency environment
- 3rd CTDT forum conducted in UK (30th April) – 30+ pharmas were represented

2012/2013 → **Last 9 months** → **Now**

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REGULATORY TIMELINE

EUROPEAN MEDICINES AGENCY (EMA)

22 Nov 2012
EMA CTDT workshop

24 Jun 2013
Draft Policy 70

1 Oct 2013
Public Consultation closed

13 Nov 2013
Progress Update

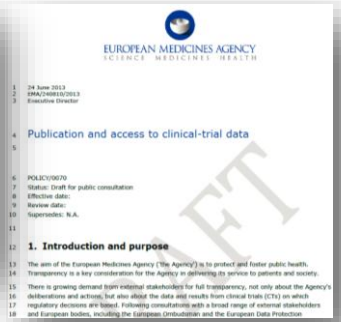
17 Dec 2013
Notice of Delay

June 2014
Management Board Meeting

Agenda – Workshop on clinical trial data and transparency

22 November, 13.00-17.00, European Medicines Agency, London, room 2A

Item	Agenda	Name	Timing
1.	Registration and light snacks		12.00 – 13.00
2.	Welcome	Guido Rasi	13.00 – 13.10
3.	Introductory statements from:		
	Assistant European Data Protection Supervisor	Giovanni Buttarelli (confirmed)	13.15 – 13.20
	European Ombudsman representative	Gerhard Grill (confirmed)	13.20 – 13.25
4.	Panel introductions by moderator	Mark Walport (confirmed)	13.25 – 13.30
5.	Panel discussion with contributions from:		13.30 – 15.00
	Academia / Cochrane Collaboration	Peter Gøtzsche (confirmed)	
	Pharmaceutical industry / EFPIA	Susan Forda (confirmed)	
		Neil Weir (confirmed)	
	Journalists and medical journal editors	Ben Goldacre	



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SCIENCE MEDICINES HEALTH

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DRAFT

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SCIENCE MEDICINES HEALTH

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European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

Press release

13/11/2013

European Medicines Agency updates on development of its policy on publication and access to clinical-trial data

In-depth analysis of more than 1000 stakeholders' comments received on draft policy currently underway

The European Medicines Agency is currently reviewing and analysing more than 1,000 comments received during the public consultation on its draft policy on publication and access to clinical-trial data, which ran from June to end of September 2013.

The public consultation on the policy has generated input from an unprecedented range of stakeholders. Patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies and a range of others sent their comments to the Agency. Many of the contributors provided detailed in-depth comments, some of them substantial, some of them technical, including suggestions relating to methodological and technical aspects of the implementation of the policy.

The Agency is grateful for this exceptional contribution from its stakeholders. As part of its collaborative approach to developing a methodology for the release of clinical-trial data with its stakeholders, the Agency is currently devoting attention to all comments received and reaffirms its commitment to transparency and the principles of publication

CLINICAL TRIAL DATA TRANSPARENCY

INDUSTRY POSITIONING

PhRMA
RESEARCH • PROGRESS • HOPE

efpia
European Federation of Pharmaceutical Industries and Associations

Principles for Responsible Clinical Trial Data Sharing

Our Commitment to Patients and Researchers

Biopharmaceutical companies are committed to enhancing public health through responsible sharing of clinical trial data in a manner that is consistent with the following Principles:

- **Safeguarding the privacy of patients**
- **Respecting the integrity of national regulatory systems**
- **Maintaining incentives for investment in biomedical research**

1. Enhancing Data Sharing with Researchers
2. Enhancing Public Access to Clinical Study Information
3. Sharing Results with Patients Who Participate in Clinical Trials
4. Certifying Procedures for Sharing Clinical Trial Information
5. Reaffirming Commitments to Publish Clinical Trial Results

http://phrma.org/sites/default/files/pdf/PhRMAPrinciplesForResponsibleClinicalTrialDataSharing.pdf

Balancing the different dimensions of responsible clinical data sharing

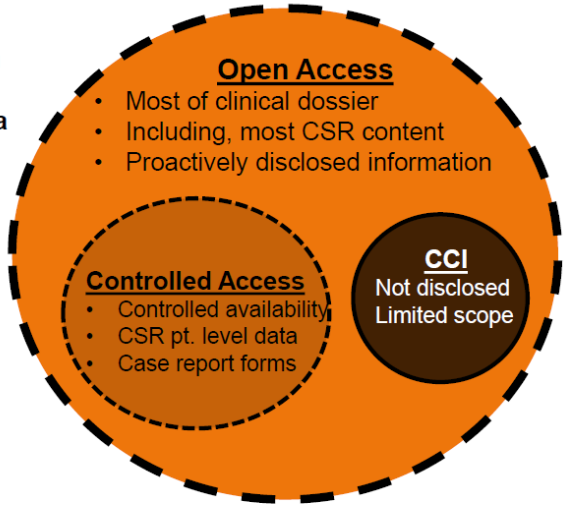
efpia

EMA Proactive Transparency Proposals

24 June 2013 Draft Policy

Industry's primary concerns:

Safeguarding Protected Personal Data (PPD)



Ensuring robust process for redacting CCI

efpia

Source: Sue Forda, Chair, EFPIA SRMPC. Slides from SAS Data Transparency Forum, Marlow, 30th April 2014

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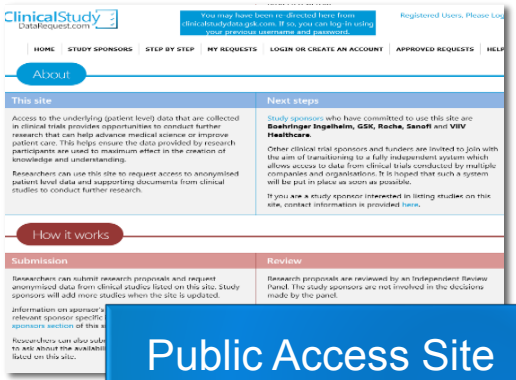
HIGH LEVEL OVERVIEW – 3 MAIN COMPONENTS



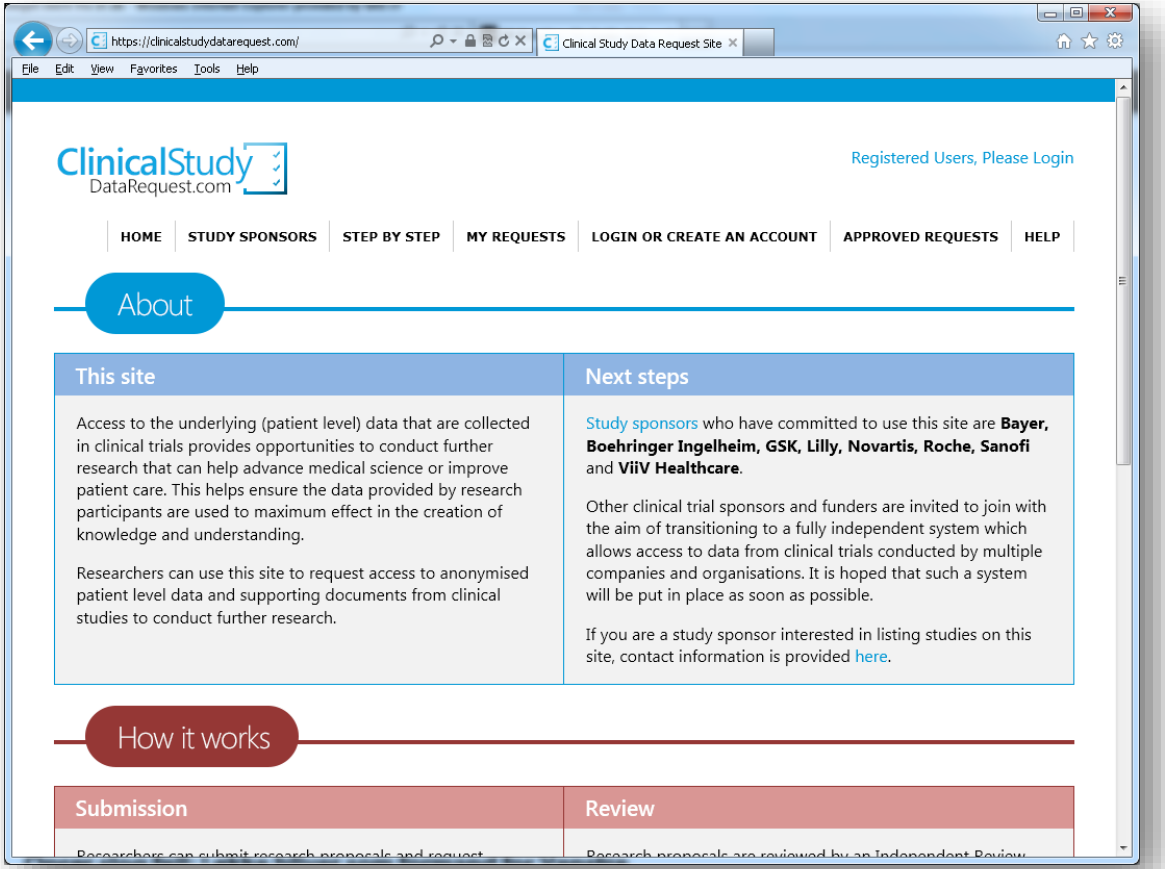
Public Access Site

Independent Review Panel

Researcher Site

MULTI-SPONSOR DATA REQUEST SITE

- Bayer
- Boehringer Ingelheim
- GSK
- Lilly
- Novartis
- Roche
- Sanofi
- ViiV Healthcare



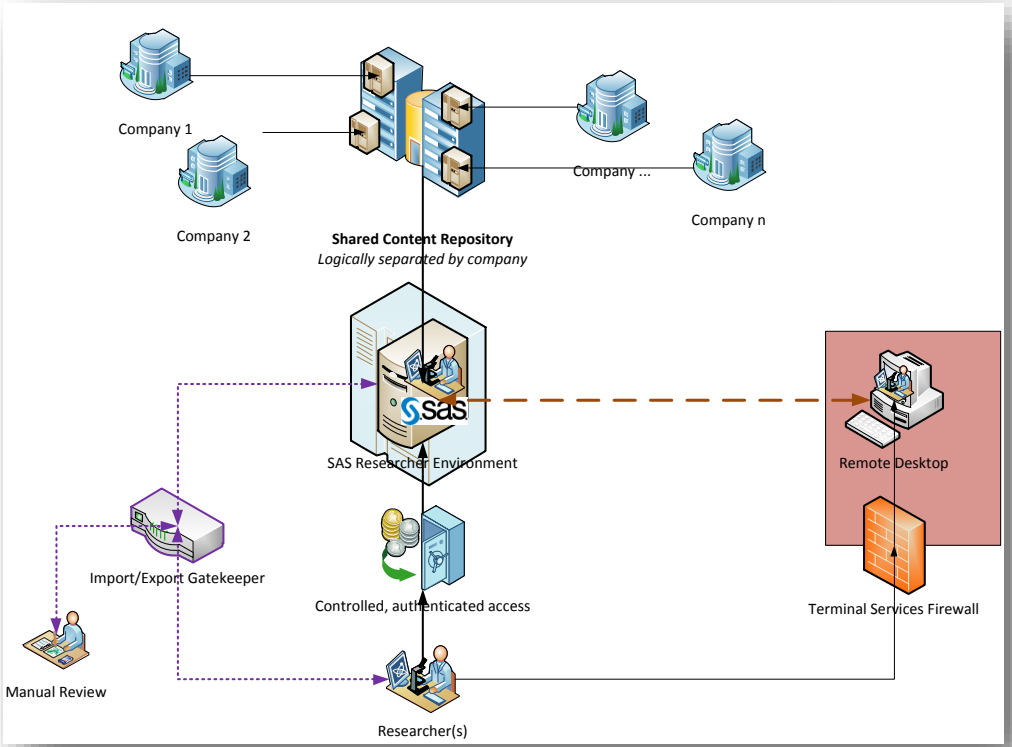
https://clinicalstudydatarequest.com/

MAIN CAPABILITIES

- Proposal request system and approval process
- User registration process
- Data transfer into the transparency system from sponsor systems
- Researcher access to analytical tools
  - SAS
  - SAS Visual Analytics
  - Others as needed
- Training / Help / Videos / tech support
- Managed extraction of scripts and results from system
  - Data cannot be extracted / exported

Implementation principles
- Hosted by SAS
- Secure data repository
- Easily accessible to researchers
- Ongoing system monitoring and support

MULTI-SPONSOR ENVIRONMENT



- Shared environment
- Logically segregated sponsor data
- Researcher access to multiple sponsors' information
- Research Project-based model
- Supports requests for multiple sponsors' data
- Distributed costs for hosting, hardware, administration and support
- Supports low-entry cost for non-profits

TOPICS

WHAT ARE THE CURRENT TOPICS BEING DISCUSSED?

- **De-identification:** ensuring appropriate de-identification of data (ensure protection of patient privacy)
- **Approval criteria:** define common agreed criterias for approval of research requests
- **Informed consent:** respect the boundaries of patients informed consent
- **Independant Review Panel (IRP):** what competencies should be represented?
- **Commercially Confidential Information (CCI):** what information can be CCI classified?
- **Data standards:** pooling of clinical trial data across multiple trial programs and sponsors
- **Publication of results:** how will sponsors manage secondary publication of research, based on sponsor's data?
- **Amount of requests:** how many requests have been submitted by researchers?
- **Analysis:** challenges with Re-analysis, comparative analysis and meta analysis. Concern of secondary analysis without proper oversight could damage sponsor.
- **Single sponsor vs. Multi-sponsor environment:** what are the key differences?
- **Multi-sponsor environment:** will the multi-sponsor data transparency environment become a global repository for Clinical Trial data of regulatory approved pharmaceutical products?
- **Future:** can we anticipate that the CTDT MSE will be 'connected' to other bio-informatic databases…?

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TAKE AWAY - SIX KEYS TO SUCCESS

1. Access to a listing of available studies combined with a user-friendly data request process
2. Independent review panel that grants or denies data access to researchers
3. A secure computing environment with advanced analytics built in
4. Access to patient-level data, de-identified as appropriate for the research at hand
5. Protection of data from uncontrolled distribution or misuse
6. The flexibility to analyze data from a single sponsor or multiple sponsors in the same environment

Source: http://www.sas.com/en_us/whitepapers/ready-for-clinical-trial-data-transparency-107119.html?utm_medium=RSS&utm_source=white-paper

Thank you!